

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Thomas J. Guttuso, Jr.	)	
			)	Examiner:
Serial No.	:	10/609,176	)	Shirley Gembeh
			)	
Cnfrm. No.	:	7781	)	Art Unit:
			)	1614
Filed	:	June 27, 2003	)	
			)	
For	:	METHOD OF TREATING SYMPTOMS OF	)	
		HORMONAL VARIATION, INCLUDING HOT	)	
		FLASHES, USING TACHYKININ RECEPTOR	)	
		ANTAGONIST	)	
			)	

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RESPONSE UNDER 37 C.F.R. § 1.111

**Mail Stop: Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

In view of the following remarks, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1, 2, 4, and 6-21 under 35 U.S.C. § 112 (first paragraph) as lacking written descriptive support is respectfully traversed.

The U.S. Patent and Trademark Office has taken the position that the recitation of NK<sub>2</sub> receptor antagonists and NK<sub>3</sub> receptor antagonists in the specification is insufficient to support use of the genus as claimed. Applicant disagrees for several reasons.

Firstly, it is clear from the description of the present invention that applicant intended to describe and claim the use of the class of compounds known as NK<sub>2</sub> receptor antagonists and NK<sub>3</sub> receptor antagonists in the treatment of hot flashes. Persons of skill in the art would readily appreciate as much.

Secondly, the specification recites by name two exemplary NK<sub>2</sub> receptor antagonists and two exemplary NK<sub>3</sub> receptor antagonists. But the disclosure of specific species of NK receptor antagonists is *not* limited to these four exemplary species. Indeed, the specification recites, through the incorporation by reference of several U.S. patent documents,

hundreds of other NK<sub>2</sub> receptor antagonists and NK<sub>3</sub> receptor antagonists. In particular, U.S. Patent No. 5,635,509 to Jacobs et al. describes a series of nonpeptide heterocyclic NK<sub>2</sub> receptor antagonists (*see* formula I described therein and at col. 1:50-52); U.S. Patent No. 6,150,325 to Arcamone et al. describes a series of bicyclic peptide NK<sub>2</sub> receptor antagonists (*see* formula I described therein and at col. 5:40-44); U.S. Patent No. 5,731,309 to Bernstein et al. describes a series of nonpeptide heteroalkyleneamine NK<sub>2</sub> receptor antagonists (*see* formula I described therein and at col. 1:52-54); U.S. Patent No. 5,554,641 to Horwell describes a series of NK<sub>3</sub> receptor antagonists (*see* formula I described therein and at col. 9:66-67); U.S. Patent No. 5,846,965 to MacKenzie et al. describes a series of 3-aza- and 3-oxa-piperidone tachykinin antagonists that are active at one or more of the receptors, including NK<sub>2</sub> and NK<sub>3</sub> (*see* formula I described therein and col. 1:48-52); and U.S. Patent No. 6,242,438 to MacKenzie et al. describes a series of 3-azatidinylalkyl-piperidines and 3-azatidinylalkyl-pyrrolidines that are active at one or more of the receptors, including NK<sub>2</sub> and NK<sub>3</sub> (*see* formula I described therein and col. 1:47-50, 66:45-48 (identifying compound have NK<sub>3</sub> activity)). Each of these patents is expressly incorporated by reference in its entirety into the specification (*see* pages 6-8 of the present application).

In addition to those prior art references incorporated by reference in the present application (and listed above), the prior art and post-filing date art contains descriptions of numerous other classes of NK<sub>2</sub> receptor antagonists and NK<sub>3</sub> receptor antagonists. Use of such compounds in the presently claimed invention is also clearly contemplated (*see* present application at page 8, lines 12-14). A non-exhaustive list of these other compounds includes those recited in the following references: U.S. Patent No. 5,521,156 to Owen et al., which describes a class of cyclic peptides active as NK<sub>2</sub> receptor antagonists; U.S. Patent No. 6,365,602 to Bernstein et al., which describes a class of N-substituted naphthalene carboxamides active as NK<sub>2</sub> antagonists (and dual NK<sub>1</sub>/NK<sub>2</sub> antagonists); U.S. Patent No. 6,613,770 to Farina et al., which describes a class of quinoline derivatives that are selective or dual NK<sub>2</sub> and NK<sub>3</sub> receptor antagonists; U.S. Patent No. 6,465,489 to Aulombard et al., which describes a class of ureidopiperidine derivatives that are active as NK<sub>3</sub> receptor antagonists; and U.S. Patent No. 6,710,042 to Bichon et al., which describes a class of NK<sub>3</sub> receptor antagonists. As these are U.S. patent documents, copies of these supporting documents are *not* enclosed herewith.

From the foregoing, it should be appreciated that numerous NK<sub>2</sub> and NK<sub>3</sub> antagonists were known in the art prior to the priority filing date of the present application and additional members of these subgenera have been described in the patent literature since the priority filing date. Because persons of skill in the art would readily appreciate—based on the written description of the invention in the present application—that the members of these subgenera are useful in practicing the claimed invention, persons of skill in the art would appreciate that the applicant was, in fact, in possession of the presently claimed invention. Hence, the present application provides written descriptive support for the claimed invention.

Thirdly, the PTO position is at odds with recent Federal Circuit decisions concerning the use of known compounds. *See Capon v. Eshhar*, 418 F.3d 1349, 1358, 1360-61, 76 USPQ2d 1078, 1084-85, 1087 (Fed Cir. 2005) (inclusion of known DNA sequences in specification is not required to satisfy written description requirement); *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) (no *per se* rule that a biological macromolecule of known structure must be recited in the specification to support its use in the claimed invention). Because the subgenera of NK<sub>2</sub> receptor antagonists and NK<sub>3</sub> receptor antagonists possessed *known* structures and *known* activities, there is simply no need for an applicant to include a laundry list of species in the specification.

For these reasons, the rejection of claims 1, 2, 4, and 6-21 as lacking written descriptive support is improper and should be withdrawn.

Applicant notes the objection to claims 3 and 5. Because claim 1, 2, and 4 are allowable for the reasons noted above, and claims 3 and 5 depend from these claims, the objection should also be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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